

## REMARKS

### Claim Rejections - 35 USC §103

Claims 3, 5, and 7 to 9 as being unpatentable over Jindrich et al. in view of DeRosch et al has been maintained. Applicants respectfully submit that these claims are not obvious from those prior art references and that rejections have been maintained improperly.

Pages 2 and 3 of the final office action states the following:

Applicant asserts that Jindrich while disclosing a labeled cyclodextrin (13C-methyl labeled) does not disclose any other labeled cyclodextrins having a modified group as claimed by Applicant. Hence, 13C-methyl labeled cyclodextrin is not encompassed in the instant invention.

The amended claim is directed to a 13C-labeled poly-or oligo saccharide comprising two possible components (1) 13C-cyclodextrin OR (2) at least one sugar molecule of the poly-or oligo-saccharide that is modified with at least one modifying group (see independent claim 5). Hence, the prior art encompasses the instant invention because it discloses 13 C-cyclodextrin. The cyclodextrin component of Applicant's claim does not require that it contain as a modifying group. Furthermore, it is noted that claim 9 which depends upon independent claim 5 states that the 13C-labeled poly-or oligo saccharide may be 13C-cyclodextrin or beta-galactosyl-13C-maltoligosaccharide. Thus it is not required that the cyclodextrin be modified.

In the first paragraph above, the Office Action characterizes Applicants' assertion that <sup>13</sup>C-methyl labeled cyclodextrin is not encompassed in the instant invention (or more correctly, the claims of the present invention do not read on the prior art because <sup>13</sup>C-labeled cyclodextrin and other claimed molecules are not disclosed in Jindrich). However, in the second paragraph, the Office Action shifts gears and asserts that <sup>13</sup>C-cyclodextrin is disclosed by the prior art without giving any evidence and further asserts that because Applicants claim <sup>13</sup>C-cyclodextrin, the claims of the present invention are obvious. The Office Action seems to replace what is actually disclosed (<sup>13</sup>C-methyl-cyclodextrin) by Jindrich with what is incorrectly alleged to be disclosed (<sup>13</sup>C-cyclodextrin). And this allegation is given without any evidence or justification. As Applicants have described in the previous office action dated November 4, 2002, Jindrich et al does describe <sup>13</sup>C-methyl-cyclodextrin but does NOT describe <sup>13</sup>C-cyclodextrin (see page 79, last complete paragraph). That is, in terms of labeled cyclodextrin, Jindrich et al. only gives an

example of creating  $^{13}\text{C}$ -methyl-cyclodextrin by methylating cyclodextrin with  $^{13}\text{C}$ -enriched dimethyl sulfate. It does not teach any other labeled cyclodextrins or suggest making other  $^{13}\text{C}$  labeled-compounds. Neither the previous Office Action dated June 4, 2002 nor this Final Office Action has given any evidence or justification that  $^{13}\text{C}$ -cyclodextrin or other labeled compounds other than  $^{13}\text{C}$ -methyl-cyclodextrin are disclosed, taught, or suggested in Jindrich et al. If  $^{13}\text{C}$ -cyclodextrin is purported to be described in Jindrich et al., Applicants respectfully request that the Examiner point out unambiguously where that is.

Further note that  $^{13}\text{C}$ -methyl-cyclodextrin disclosed in Jindrich et al. is not included in claim 3, 5, and 7 to 9 because claim 5 claims " $^{13}\text{C}$ -cyclodextrin or oligosaccharide or polysaccharide being modified with at least one modifying group, wherein said sugar molecule or modifying group is  $^{13}\text{C}$ -labeled, and said modifying group is selected from a group consisting of a galactosyl group, a digalactosyl group, an alkoxyl group, a carbamoyl group, a pyrimidino group, an ethylidene group, and a benzylidene group." No alkyl group, which would include the methyl group of  $^{13}\text{C}$ -methyl-cyclodextrin, is claimed as modifying group in claim 5.

Thus, claim 5 and dependent claims 3 and 7 to 9 do not read on Jindrich et al. for the foregoing reasons.

With regard to DeRosch, the Final Office Action states on page 3 as follows:

It is noted that Applicant asserts that DeRosch describes adding the cyclodextrin to the radiopharmaceutical kits, not radiolabeling the cyclodextrin directly.

DeRosch was cited because it discloses the use of both modified and unmodified cyclodextrins which the original claim required. In particular, it illustrates how cyclodextrins may be modified.

The Final Office Action seems to apply non-sequitur arguments by not rebutting our assertion but merely restating that DeRosch discloses the use of both modified and unmodified cyclodextrins and illustrates how cyclodextrins may be modified. DeRosch does not disclose, suggest, or teach labeling cyclodextrins or even modifying cyclodextrins; it discloses adding cyclodextrins or other cyclic oligosaccharides to radiopharmaceutical kits. To put it more directly, DeRosch does not label cyclodextrins but merely adds cyclodextrins to

radiopharmaceutical kits to stabilize the components in the kits. See, for example, column 1, lines 5 to 12,

The present invention relates to the stabilization of radiopharmaceutical preparations and to the stabilization of components of radiopharmaceutical kits. In particular, the present invention relates to stabilization of lyophilized components of radiopharmaceutical kits by the **addition of a cyclic oligosaccharide, such as a modified or unmodified cyclodextrin, to the kit.**

(Emphasis added.)

and column 2, lines 63 to column 3, line 5,

It has been discovered that cyclic oligosaccharides act as effective stabilizers for radiopharmaceutical kits. In particular, modified or unmodified cyclodextrins have been found to provide superior stabilization qualities. From preliminary studies, it is believed that **the addition of cyclic oligosaccharides, such as modified or unmodified cyclodextrin, to the radiopharmaceutical kits helps to inhibit oxidation of the kit components and to inhibit the volatilization of generally non-lyophilizable components.** However, other mechanisms of stabilization can not be entirely ruled out at this time.

(Emphasis added.)

No where does DeRosch describe labeling or modifying cyclodextrins. If cyclodextrin is purported to be labeled or modified in DeRosch, Applicants respectfully request that the Examiner point out unambiguously where that is.

Thus, we assert that DeRosch by itself or in combination with Jindrich does not disclose, teach, or suggest the invention as claimed in claim 5. A person of ordinary skill in the art would not have found the present invention as claimed obvious from the cited prior art references.

#### Claim Rejection – 35 USC §112

Claim 8 has been rejected for being indefinite. Claim 8 has been amended to depend correctly on claim 5.

Applicants believe that all pending claims are in allowable condition for the foregoing reasons and request that all pending claims be allowed.